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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999D–1540] (formerly Docket No. 99D–1540)

Guidance for Reviewers on Evaluating the Risks of Drug Exposure in Human Pregnancies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for reviewers entitled "Reviewer Guidance: Evaluating the Risks of Drug Exposure in Human Pregnancies." This guidance is intended to help FDA staff evaluate human fetal outcome data generated after medical product exposures during pregnancy. The goal of such evaluations is to assist in the development of product labeling that is useful to medical care providers when they care for patients who are pregnant or planning pregnancy. The review of human pregnancy drug exposure data and assessment of fetal risk (or lack of risk) requires consideration of human embryology and teratology, pharmacology, obstetrics, and epidemiology. Consequently, FDA staff also are encouraged to consult with experts in these fields, as appropriate.

The guidance announced in this document finalizes the draft guidance entitled "Guidance for Reviewers: Evaluation of Human Pregnancy Outcome Data" announced in the **Federal Register** of June 4, 1999.

DATES: Submit written comments or electronic comments on agency guidances at any time.

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ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist either office in processing your requests. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dianne L. Kennedy, Center for Drug Evaluation and Research (HFD–020), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5162, e-mail: *kennedyd@cder.fda.gov*, or Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6190, e-mail: *stifano@cber.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for reviewers entitled "Reviewer Guidance: Evaluating the Risks of Drug Exposure in Human Pregnancies." The guidance provides FDA staff with critical factors to consider when evaluating data on the effects of drug exposure during human

pregnancies. It also describes the sources of human data on gestational drug exposures and available resources for more information. The guidance is intended to provide FDA reviewers with a standardized and scientific approach to the evaluation of the effects of human gestational drug exposures.

In the **Federal Register** of June 4, 1999 (64 FR 30040), FDA announced the availability of a draft version of the guidance entitled "Guidance for Reviewers: Evaluation of Human Pregnancy Outcome Data." When the draft guidance was published, FDA requested comments on the document. Three public comments were received. The comments were supportive of the agency's efforts to provide this type of guidance. However, the comments also recommended revision/clarification of several sections, as well as provided a number of suggestions of a more technical nature. Additionally, comments regarding the draft guidance raised the following three broader concerns: (1) That it contained redundant information already presented in the guidance for industry entitled "Establishing Pregnancy Exposure Registries" (draft: 64 FR 30040, June 4, 1999; final: 67 FR 59528, September 23, 2002), (2) that it focused too much on general epidemiologic issues, and (3) that it overemphasized the utility of pregnancy registries without a balanced review of the strengths of other data sources for evaluating pregnancy outcome data.

Based on these comments and discussions with FDA's Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs on June 3, 1999 (64 FR 23340, April 30, 1999), and March 28 and 29, 2000 (65 FR 10811, February 29, 2000), and with other interested parties, the draft guidance has been revised and finalized. The name has been changed from "Evaluating Pregnancy Outcome Data" to "Evaluating the Risks of Drug

Exposure in Human Pregnancies" to reflect more accurately the information contained in the guidance.

This guidance is being issued consistent with FDA's good guidance practice regulation (21 CFR 10.115). The guidance represents the agency's current thinking with regard to evaluating data on the effects of drug exposure during pregnancy. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: 4/19/05
April 19, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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